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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,075	12/17/2003	Perry F. Renshaw	04843/117002	1400
21559	7590	01/19/2007	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			CRANE, LAWRENCE E	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/740,075

Applicant(s)

RENSHAW ET AL.

Examiner

L. E. Crane

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 3, 2006 (amdt).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 7-30 is/are pending in the application.
- 4a) Of the above claim(s) 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 7-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims **4 and 6** have been cancelled, claims **1, 2, 12, 17, 18, 22, 27 and 28** have been amended, the disclosure has not been amended, and no new claims have been added as per the amendment filed November 3, 2006. No supplemental Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1-3, 5 and 7-30** remain in the case.

Newly submitted claim **30** directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the subject matter of the noted claim is directed to subject matter which is beyond the scope of the originally filed and searched claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim **30** withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. §1.142(b) and MPEP §821.03.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant argues that because claim **30** is dependent and is a linking claim, that the claim should be included within the instant prosecution based on applicant's expectation that claim **1** will be found allowable. Examiner respectfully disagrees for the reasons of record and notes that the subject matter of claim **30** was not part of the original search. Examiner also notes that the term "comprising" in claim **1** and in other independent method claims means that, in the event of a finding of allowability, the combination of the instant method claim (or claims) allowed with any other method including part or all of the subject matter proposed in claim **30**, would be infringed; i.e. claim **30** is unnecessary for applicant to defend allowed subject matter claimed broadly. Alternatively Examiner suggests that applicant either cancel claim **30** without prejudice and file a divisional, or file a continuation. Either suggested action would permit the subject matter of claim **30** to be searched and included within the subsequent prosecution.

Claims **1-3, 5 and 7-29** remain under examination.

Note to applicant: when a rejection or objection refers to a claim X at line y, the line number is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims 1-3, 5 and 7-29 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

Examiner has inspected the disclosure and Figures 1 and 2, and finds therein what appears to be data concerning the reactions to the administration of CDP-choline by a single human host, apparently a 33 year old subject who appears to be addicted to or habituated to, alcohol, cocaine and tobacco and who consumes caffeinated beverages, a possible additional habituation. Applicant has claimed broadly the treatment of sleep deprivation in all human and mammalian hosts, but has not provided sufficient exemplifying data to support such a broad scope of subject matter. Examiner suggests that applicant needs to establish individually the effective treatment of specific sleep related disease conditions (insomnia, narcolepsy, etc. etc.) by testing appropriate groups of subjects (night shift workers, interns doing 24 hour stints, etc.). Alternatively examiner suggests applicant may elect to demonstrate the effective treatment of specific-drug addicted hosts who suffer from sleep deprivation(s). In any event the instant data set is simply inadequate to support the instant patent claims because of the lack of showing that the claimed effects of CDP-choline administration are common to a reasonable number of similarly situated hosts in need of such treatment.

Because applicant has provided some data, applicant may elect to supply additional data using a declaration under 37 C.F.R. §1.132. Alternatively applicant's counsel may advise applicant concerning other strategies for maintaining the instant subject matter under prosecution until such time that sufficient data has been supplied to adequately support grant of a patent claim or claims.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant quotes the MPEP to support the assertion that examiner is questioning the truth of applicant's submission. This is an inaccurate statement. Applicant is requested to re-read the rejection wherein examiner suggests that applicant must submit additional data to adequately support the scope of the proposed claims. The rejection of record is an enablement rejection, not a written description rejection.

Applicant, after summarizing applicant's view of the disclosure's contents, concludes that "[a]pplicant's have enabled the instant claims." Examiner respectfully disagrees for the reasons of record. The data obtained from applicant's single tested host is simply not sufficient to convince Examiner that the effects reported are not specific to the single host and the particular condition of said host. Applicant is requesting examiner to believe the extrapolations, as embodied by the claims, from the supplied data without providing data to support those extrapolations.

Applicant then notes the MPEP at §2164.02 to the effect that no examples are required. Examiner respectfully disagrees and notes that there is a string of cases at MPEP §2107.03 including *Ex parte Balzarini*, 21, USPQ 2d 1892, 1894 (BPAI, 1991) outlining a different policy for medicinal claims. The first opinion in *Balzarini* stands for the proposition that claims directed to medicinal treatments of diseases in highly unpredictable art areas are properly rejected under 35 U.S.C. §112, first paragraph as lacking adequate enablement, in the absence of sufficient test data in support of the efficacy of the alleged treatment. See MPEP at 2107.03 (p. 2100-44, col. 2, in the August, 2001 revision). Based on this portion of the MPEP Examiner understands that the PTO is empowered to require a showing of sufficient data to adequately support claimed medicinal activity. The data does not have to be human test data. And finally Examiner notes that treatments of disease conditions of the nervous system, including diseases of the human brain, remain one of the most unpredictable areas of the medical arts.

Claims **1-3, 5 and 7-29** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: the breadth of many of the claims is excessive because of the presence of generic terms including "treating a sleep disorder," and "increasing cognitive function."

B. The nature of the invention: the invention is directed to treatment of sleep or sleep-related disorders including those disorders caused by drug addictions.

C. The state of the prior art: the administration of CDP-choline is associated in some prior art references with the effective amelioration of insomnia, particularly in elderly hosts. See the prior art-based rejections below.

D. The level of one or ordinary skill: the level of the ordinary practitioner is variable, because the administration of CDP-choline is known to be effective in some hosts, but the remainder of the claimed active ingredients have not been shown herein to have similar activities.

E. The level of predictability in the art: the art of treating sleep disorders is highly variable in its predictability because of the large array of different causes or circumstances under which it is observed to occur, both known (drugs, shift work, etc.) and unknown (aging, physical injury, etc.).

F. The amount of direction provided by the inventor: referring to Figures 1 and 2, it appears that applicant has only tested the administration of CDP-choline on a single human host who is apparently afflicted with multiple chemical dependencies including to alcohol, cocaine and caffeine.

G. The existence of working examples: there appears to be only a single working example and no clear indication discernable by examiner concerning what particular sleep disorder or disorders were being treated in this particular host.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in light of the indefiniteness and functionality of the claims and because the exemplary evidence is so limited in quantity, and consequently the minimum necessary guidance concerning various different active ingredients and their application to various different sleep disorder treatments, is simply absent.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant argues that prospective enablement with a single working example is sufficient. In light of applicant's admission of the numerous conditions afflicting the single host tested, Examiner remains skeptical in the absence of additional working examples, examples wherein the test host need not be human but may be lower mammalian or cells in culture.

Applicant alleges that the level of skill of the ordinary practitioner is directly correlated with the level of education of said practitioner. Examiner respectfully disagrees, because even the most highly educated practitioner would be unable to practice the instant claimed methods without undue experimentation as a consequence of the insufficient guidance provided by single working example of the instant disclosure. Applicant has interesting theories and substantial prospective disclosure expanding on said theories, but not enough data to support any one of the instant independent claims.

Applicant argues incorrectly that MPEP §2164.03 governs the instant claims. See above wherein the MPEP at §2107.03 is cited as the appropriate location for guidance concerning analysis of predictability and the other Wands enablement prongs in medicinal method of treatment cases.

Examiner has reviewed applicant's arguments and finds them to be inappropriately based on §2164.03 of the MPEP. Examiner has also reviewed the Wands analysis and continues to agree with the thrust thereof in light of the standards of the MPEP at §2107.03. Examiner encourages applicant to the degree practical to provide any and all additional relevant test data available or known in the prior art.

Examiner is puzzled by applicant's insistence the adenosine is appropriate in claim 17 ("increasing cognitive function is a sleep deprived mammal") when there are two references in the instant case teaching that adenosine contributes to the induction of sleep. Applicant is referred to page 268, column 1, of **Radulovacki et al.** (PTO-1449 ref. C31) wherein reference is made to prior art wherein "... some experimental evidence suggests that adenosine may have a role in sleep." See also **Satoh et al.** (PTO-1449 ref. C35) at page 155, column 2 wherein a similar disclosure has been made.

For the above stated reasons in response to applicant's arguments the instant ground of rejection has been maintained.

Claims 1-2, 12-15, 17, 19, 22, 27 and 28 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 at line 5, the acronym abbreviation "CDP-choline" has not been completely named rendering the claim incomplete. Applicant is respectfully requested to insert the complete chemical name followed by the abbreviation at the first occurrence in the claims; e.g. -- cytidine diphosphate choline (CDP-choline) --. All subsequent occurrences of the same compound in dependent claims and presently represented by the same abbreviation need not be modified. See also claims 12, 17, 22 and 27 wherein newly added abbreviations may be present.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Examiner notes with appreciation the amendments made but respectfully requests the noted amendment.

In claim 1 at line 3 the term "compound comprising" is indefinite because the subsequent list of compounds are all named as separate compounds rather than substituent moieties of a larger molecular species, and because the larger molecular species implied by the term "comprising" (including) is not subsequently defined thereby leaving the metes and bounds of the claimed subject matter incomplete. See also claims 12, 15, 17 and 22 wherein the same problem reoccurs.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicants argue that one of ordinary skill would understand the metes and bounds of the term "compounds comprising." Examiner respectfully disagrees, and renews the request made in the rejection supra to avoid the term "comprising" because of the incorrect implication of an incomplete listing of active ingredients and/or an incomplete disclosure of the identity of the active ingredients.

Applicant's attention is drawn to **Pekkanen** (PTO-892 ref. V) wherein analysis of several different sources of information about the relationship of sleep, light exposure, melatonin generation during sleep, and correlations with cancer, and the effects of light induced disruptions of the human body's master clock, are noted. This reference is deemed to support Examiner's view that the subject of sleep and the treatment of sleep disorders and sleep-related disease conditions is very complex, and that apparently straightforward extrapolations of the kind advanced herein need to be well supported by data in order to avoid being fooled by unseen and untested effects.

In claim 12 at lines 4-5, the term "is not compromised by an existing physical condition" is an improper negative limitation because the particular "existing physical limitation[s]" have not been specified in the claim.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

The above noted term is an improper negative limitation. Applicant is respectfully requested to either delete the term or define the specific physical conditions being excluded.

In claim 13 the term "said sleep disorder is caused by a substance abuse disorder" lacks proper antecedent basis. Examiner suggests introduction of the term -- further comprising -- in order to effectively address this expansion of the subject matter definition of claim 12. Said term also renders the claim incomplete because the particular "substance abuse disorder" has not been specified. See also claim 23 in re its dependence from claim 22.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant has argued that the noted claim does not lack proper antecedent basis and that the particular "substance abuse disorder" need not be defined. Is applicant claiming being able to treat the effects of the "substance abuse disorder" when said term reads on the excessive consumption of substances including air, water, fritos, fish and chips, or triple cheeseburgers on sleep? Appropriate clarifying amendments are again requested.

Claim 14 is incomplete because the list of abused substances is not preceded by the term -- caused by --. See also claim 24.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant is respectfully requested to amend as suggested to insure proper grammatical structure.

In claim 19 the term "not caused by a substance abuse disorder" renders the claim incomplete because the particular substance abuse disorder(s) has(have) not been specified.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant is requested to note that the cited term is an improper negative limitation and to define with particularity the condition(s) being treated.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-3, 5 and 7-29** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-16** of U. S. Patent No. **6,103,703** (PTO-1449 ref. **A10**). Although the conflicting claims are not identical, they are not patentably distinct from each other because claimed the methods of treatment, “increasing cognitive functions in a sleep deprived mammal, treatment of insomnia, or other cognitive dysfunction” versus “preventing or ameliorating a stimulant induced disorder,” and wherein the alleged active ingredients are selected from a cytidine- or a 2'-deoxycytidine-5'-nucleotide, are directed to substantially overlapping subject matter.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant argues that the '703 patent is directed to patentably distinct subject matter. It is well known that excessive consumption of caffeine causes several undesirable effects including “[w]akefulness, restlessness, anorexia, vomiting, dehydration, ...” (emphasis added) as noted at page 2624 of The Merck Manual (17th Edition). Therefore, it is clear to Examiner that the '703 patent claims directed to “... methods of preventing or ameliorating a stimulant induced disorder” undoubtedly read on the treatment of sleep disorders caused by substances including caffeine, a substance listed in instant claim **24** at line 2. The above grounds of rejection are maintained and the request for a terminal disclaimer or other appropriate action is respectfully repeated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

“A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

Claims 1-3, 5, 7-14, 16-21 and 27-29 are rejected under 35 U.S.C. §102 (b) as being anticipated by **Fernandez** (PTO-1449 ref. C47).

Applicant is referred to page 1073 of the cited reference at column 1, lines 11-17 of the "Summary," and particularly to line 15 wherein the administration of CDP-choline to treat insomnia is specifically taught. See also page 1076, column 2, next to last line and associated explanatory text.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant argues that "insomnia" is not being treated as claimed herein in Fernandez on the basis that "methods of normalizing the sleep/wake cycle" does not read on treating insomnia, and that "insomnia is an inability to sleep." Examiner agrees that insomnia is correctly defined but respectfully disagrees that the instant claims are not anticipated by Fernandez. A person suffering from insomnia is suffering from a disturbance of the sleep/wake cycle. To allege otherwise is to engage in nothing more than sophisticated word games wherein applicant has elected to believe that adjusting sleep/wake cycles does not read on treating insomnia. Examiner does not agree with applicant's interpretations of the noted terms and finds that the above rejection applies to the claims as listed.

Examiner also notes Tables 6 and 7 at page 1079 of Fernandez wherein the following symptoms observed to be effectively treated by CDP-choline are as follows: "dizziness,"

“cephaleas [aka headaches],” “fatigue,” “insomnia,” “speech troubles,” “motor deficits,” “spasticity,” “[impaired] manual skill,” “walk instability,” “memory shortage,” “depressive mood,” and “[impaired] social life” as conditions effectively caused to disappear by the administration of CDP-choline to as many as 48.4% of treated patients. The instant independent claims are directed to “normalizing the sleep/wake cycle” (claims **1 and 27**), “treating a sleep disorder” (claims **12 and 22**), and “increasing cognitive function” (claim **17**). Examiner has carefully read the claims and continues to believe that Fernandez reads on the claims listed because, contrary to applicant, examiner does not believe that treating insomnia is not treating the sleep/wake cycle. In addition, Examiner sees several symptoms effectively treated in Fernandez being encompassed by the term “increasing cognitive function,” particularly including “[effective treatment of] speech troubles,” and “[effective treatment of] memory shortage.”

Claims **17, 18, 20 and 21** are rejected under 35 U.S.C. §102 (e) as being anticipated by **Wurtman et al. '415** (PTO-1449 ref. **A15**).

Applicant is referred to the **'415** reference at paragraph 0025, at paragraphs 0052-0057, and claims **7 and 8-11** wherein the administration of citicoline (CDP-choline) is disclosed to effectively treat cognitive dysfunctions including insomnia, motor coordination, and memory impairment.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Examiner has narrowed the claims alleged to have been anticipated, and notes column 1 of page 5 of the **'415** reference wherein the treatment of cognitive impairment, before or after physical injury, has been disclosed numerous times and thereby anticipates the instant claimed subject matter.

Claims **1-3, 5, 7-14 and 16-29** are rejected under 35 U.S.C. §102 (e) as being anticipated by **Ferrer International '288** (PTO-1449 ref. **B9**).

Applicant is referred to page 5 wherein the administration of pharmaceutical compositions including CDP-choline are disclosed to effectively treat a variety of symptoms related to alcoholism and withdrawal therefrom including insomnia and disorientation.

Applicant's arguments filed November 3, 2006 have been fully considered but they are not persuasive.

Applicant argues again that treating insomnia is not treating a sleep/wake disorder. Examiner respectfully disagrees noting that response supra in support of this view. Applicant also argues that claim 12 is not anticipated because said claim is directed to hosts "not impaired by an existing physical condition, i.e., alcohol withdrawal syndrome." Examiner notes claim 14 wherein the term "substance abuse disorder" is defined as "alcohol." Applicant cannot have it both ways as noted in the related rejections supra under §112, second paragraph. Until the instant claims are amended to clear up the obvious problems with overly broad functional terms and overlapping and/or incompletely defined terms, Examiner has elected to maintain the instant ground of rejection.

Claim 15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. §112 set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. §1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < <http://pair-direct.uspto.gov> >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
01/16/2007

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PATENT EXAMINER
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